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T2315-906256

IN THE UNITED STATES PATENT & TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS & INTERFERENCES

Appellant:	Frank J. Bova et al.	:	
Serial No.:	09/430,034	:	Art Unit: 3737
Filed:	October 29, 1999	:	Examiner: E. Mantis Mercader
For:	Mask System and Method for Stereotactic Radiotherapy and Image Guided Procedures	:	

BRIEF ON APPEAL

Hon. Commissioner of Patents & Trademarks
Washington, D.C. 20231

Sir:

The following Brief on Appeal is submitted in support of the appeal of the final Office Action mailed October 12, 2001, wherein the Examiner finally rejected claims 1-23.

The appeal fee of $320.00 is submitted herewith.

To the extent necessary, appellant petitions for an extension of time under 37 CFR §1.136. Please charge any additional fees due (or credit any overpayment thereof) to Deposit Account No. 50-1165 (Docket No. T2315-906256).

Respectfully submitted,

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Filed: May 3, 2002

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TABLE OF AUTHORITIES

REAL PARTY IN INTEREST

The real party in interest herein is the University of Florida Research Foundation, Inc., to which the above-captioned application is assigned by virtue of an Assignment from the inventor executed February 8, 2000, which was recorded April 25, 2000, on Reel 010,727 at Frame 0541.

RELATED APPEALS AND INTERFERENCES

The invention described in the claims on appeal herein are related to no other applications.

STATUS OF CLAIMS

The above-captioned application was filed with original claims 1-23. No claims have been cancelled. This is an appeal from the final rejection of claims 1-23, all of the claims remaining in the application.

STATUS OF AMENDMENTS

One response has been filed subsequent to the final Office Action, i.e., the Response dated January 10, 2002. The Examiner issued the Advisory Action dated January 29, 2002, stating that the Response did not place the application in condition for allowance.

SUMMARY OF THE INVENTION

The present invention relates to a device, system and method for stereotactic medical procedures. More specifically, it provides for accurate positioning (fixation) of a patient or part of a patient for carrying out medical procedures, singly or multiple times. Various medical procedures involve repeated treatments at different times. For example, application

of radiation is sometimes used for treating cancer or other conditions. Although a single application of radiation may sometimes be used, under many circumstances there are sound medical reasons to use repeated applications of radiation at different times. In addition, there are other medical procedures where precise location of patient features are required either for a one time therapeutic treatment or repeated treatments.

Although many prior art fixation or fiducial systems work very well for single fraction therapy, there exist clinical settings where fractionating the total dose, i.e., dividing the dose into many small fractions, would yield additional therapeutic advantages. In the radiotherapy procedure, however, once the reference frame has been removed from the patient the relationship between target points and the reference system is lost. Because the above procedure would require the reference frame to remain fixed to the patient through the entire course of treatment, which may last several weeks, this approach is considered inappropriate for fractionated therapy. Alternately, each fractional treatment would require a laborious and time-consuming procedure to re-determine patient position for second and subsequent treatments.

There exist several different techniques for non-invasive repeat fixation. These methods can be broken down into three basic categories. These are bite plate systems, contour realignment systems and mask systems. All of these systems have design flaws which can lead to unacceptable, and undetectable, positional errors.

In order to provide the required patient-tool tracking both the tool's position and the patient's position must be known. The most common method of tracking the patient is to place identifiable reference markers, called fiducial markers, fixed relative to the portion of the patient where treatment is desired. These markers are incorporated into the 3D image data set. They are also available for identification, again on the surface of the patient (fixed relative to the portion of the patient), at the time of the therapeutic procedure. The markers on

the patient are registered against their images in the 3D data set. This registration allows the computation of a rigid relationship between the virtual 3D patient and the real patient. Once this registration has been carried out, any movement of the patient can be tracked.

The present invention provides a new and improved method and system for localization (i.e., proper relative positioning of a patient and a medical apparatus or system) in performing medical procedures. Thus, the present invention provides a medical method including the steps, not necessarily in order, of: positioning a patient for a first medical procedure; molding a locator to external features of a patient, the locator being placed in registry with a portion of the patient using at least 3 fiducial markers that are fixed relative to the locator a first time to get precise positioning information relative to at least part of the patient the locator remaining mechanically free during this step; performing a first medical procedure on the patient, the locator remaining mechanically free during this step; after the first medical procedure, removing the locator from the patient; at a later time after the removing of the locator, re-attaching the locator to the patient, the locator again being in registry with the portion of the patient and having an identical orientation relative to the portion of the patient as when the locator was previously attached; after the re-attaching step, using the fiducial markers a second time to get precise positioning information relative to the at least part of the patient, the locator again remaining mechanically free during this step.

It is the feature of the invention, i.e., that the locator remains mechanically free during the method, that constitutes the crux of the invention. It is emphasized that, by "mechanically free", it is meant that the locator is not affixed to anything except the patient. It is not affixed, tethered or, in any way, fixedly tied to any apparatus employed in the procedure.

ISSUES ON APPEAL

Claims 9,15-16, 19 and 23 stand finally rejected under 35 USC §102(b) as unpatentable Kormos '890.

Claims 1-8, 10-14, 17-18 and 20-22 stand finally rejected under 35 USC §103 as being unpatentable over Kormos '890 in view of McLaurin '117.

An issue presented for appeal is whether Kormos anticipates every feature of the claimed invention.

A second issue presented for appeal is whether the Examiner has made out a prima facie case of obviousness within the meaning of 35 USC §103 based on the combined teachings of Kormos and McLaurin

A third issue presented for appeal is whether, assuming that a prima facie case of obviousness has been made out by the Examiner, appellants have satisfactorily rebutted the same by a valid showing of unexpected or unobvious results associated with the invention.

GROUPING OF CLAIMS

Appellant maintains that the claims do not stand or fall together. Arguments will be presented below supporting the separate patentability of the claims.

ARGUMENTS

Claims 5, 15-16, 19 and 23 stand rejected as anticipated by Kormos. The Examiner stated in the final Office action:

> *"---Regarding claims 9, 15-16, 19 and 23 Kormos et al. '890 teach a system of medical procedures, the system comprising:*
>
> *a locator attachable to a patient, having at least 3 fiducial markers thereon (col. 3, lines 31-44);*
>
> *a medical device for performing diagnostic imaging or a therapeutic medical procedure on a patient (col. 3, line 46-59);*

a sensing subsystem for sensing the positions of the fiducial markers when the patient is in a position for performing the medical procedure using the medical device (col. 4, lines 4-27);

and

wherein the locator has a registration portion for registration with a portion of a patient's body, the locator being mechanically free such that the patient is positionable without applying forces to the locator during the patient positioning, and wherein the locator is molded to fit external features of a specific patient (col. 3, lines 3-34).---"

Notwithstanding the Examiner's remarks concerning the Kormos patent, the fact remains that the reference does not disclose the concept of a "mechanically free" locator. Accordingly, the reference cannot be said to anticipate the claimed invention within the meaning of 35 USC §102. It is respectfully requested, therefore that this ground of rejection be reversed.

Claims 1-8, 10-14, 17-18, and 20-22 stand finally rejected under 35 U.S.C. 103(a) as being unpatentable over Kormos et al. '890 in view of McLaurin' 117, the Examiner stating in the final Office Action:

"---Kormos et al.'890 teach the use of thermoplastic mesh material with markers affixed on this material, placed over the area of interest for imaging guided surgery. Kormos et al. '890 do not teach the use of this material for repeated use in imaging and therapy, and wherein the area of interest is the head/face. In the same field of endeavor, McLaurin' 117 teaches the use of this material for repeated use in imaging and therapy, and wherein the area of interest is the head/face (see Abstract). It would have been obvious to one skilled in the art at the time that the invention was made to have used the thermoplastic mesh material as taught by Kormos et al. '890 in subsequent procedures or at a later time as taught by McLaurin' 117 in order to facilitate subsequent visits for treatment (see McLaurin' 117 col. 2, lines 25-51). Furthermore, it would have been obvious to one skilled in the art at the time that the invention was made, to have used this thermoplastic material over the area of interest as demonstrated by both Kormos et al. '890 and McLaurin' 117.---"

The Kormos et al '890 patent, on the other hand, relates to a detained method of performing stereotactic breast surgery by immobilizing a patient's breast, fixing the breast relative to a patient support, fixing magnetic resonant markers to the immobilization restraint, imaging the breast, specifically by magnetic resonance imaging, removing the patient from the imaging unit and performing a surgical tack along which a surgical procedure can be performed. The Kormos system is designed to immobilize an otherwise non-rigid structure, the breast, and while held into a specific position carry out a surgical procedure.

The Kormos approach differs from the claimed method in that it essentially takes otherwise non-rigid tissue and by mechanical restraint fixes it to an external reference system. Thus, note the disclosure at Col. 3,ll 12-16: "---The material (12, i. e., the 'reference mask' or "exoskeleton " as it is referred to by Kormos) is then stretched over and molded to the soft tissue region (of the patient) and affixed by clamps or other suffixing means 14 to sides of the patient support--- " (emphasis added). There can be no interpretation of this disclosure other than that the locator is rigidly fixed to the system or apparatus employed to carry out the method.

The claimed invention, on the other hand, does not require that the patient be immobilized relative to a fixed patient support; indeed, it is specified that the reference mask system is a "mechanically free" locator. Furthermore, the invention relates specifically to a system that is not only mechanically free, but also has the ability to repeatedly be fixed to the patient's rigid anatomy so that it can be used for repeat procedures. This is specifically not the focus nor the intent of the Kormos patent. In the latter the 'exoskeleton' is designed for a one-use application and then is removed and, presumably, discarded. See Col. 5,ll 0-12.

The inventive approach, conversely, takes a rigid portion of the patient's anatomy and by molding a mask to the anatomy extends this rigid anatomical feature so that external

fiducials can be applied. It is capable of, indeed, is designed for multiple uses and applications.

The Examiner calls specific attention to the disclosure of Kormos at col. 3, lines 2326 that states:

> *"exoskeleton --- is sufficiently stiff to hold the soft tissue substantially fixed relative to itself---"(emphasis Examiner's). It is not seen how this helps the Examiner's position since it only underscores the fact that the exoskeleton is fixed to the soft tissue. The Examiner has overlooked that portion of the disclosure cited above by applicant that states that the exoskeleton is also affixed by clamps or other affixing means 14 to sides of the patient support. Since the reference directly and unequivocally contraindicates the mechanically free locator of the present invention, the reference cannot be said to form a primary basis for the rejection of the claimed invention within the meaning of 35 USC 103.*

Notwithstanding the Examiner's comments regarding the disclosure of the secondary reference, the fact remains that McLaurin does not cure the deficiencies pointed out above in connection with the primary reference to Kormos. More particularly, McLaurin does not disclose or suggest the use of a 'mask' or 'exoskeleton' that is mechanically free, i.e., that is not affixed to the patient support or locator.

The McLaurin patent is, like that of Kormos, an immobilization system for fixing a patient. Applicants specifically discuss ion the specification that immobilization of the patient is not the preferred method of referencing. This technique has been applied over many years and has shown limited clinical success. The entire focus of the present invention is the use of, e.g., a facemask that is rigid and fixes the patient relative to a second reference system. The proposed improvement of this system is that the second reference system, the bar references, which is similar to those used for stereotactic head frame application, is added to the mask system. The reference bars are relative to the frame system and not the patient. The difficulty in this approach is that it is known that the patient does not repeatedly position in the reference frame mask if the mask is used for immobilization and localization. The reference

frame, the bar system, is therefore not rigidly fixed to the patient's anatomy. In the claimed approach, we specifically maintain the reference system "mechanically free" to allow the reference system to more precisely reseat to the patient's external anatomy. This separation of immobilization and localization is the key difference between the claimed invention and the prior art approaches.

The crux of the issue on appeal is whether the references relied upon by the Examiner disclose or suggest the concept of a "mechanically free" locator.

It must first be emphasized that there is no controversy as to the meaning of that term as it is defined throughout the specification. The Examiner has not voiced a rejection of the term as indefinite under 35 USC §112; moreover, the term is employed in the claims of U.S. patents nos. 5,954,647 and 5,588,430.

As to this term the Examiner stated in the final office action:

> *"---Applicant's arguments regarding the "mechanically free" locator have been fully considered but they are not persuasive because an alternative embodiment is disclosed by Kormos et al. '890 which describes the "mechanically free" locator, in col. 3, lines 23-26, by stating: "...the exoskeleton material can be a mesh of a very stiff but pliable elastic mesh which is sufficiently stiff to hold the soft tissue substantially* ***fixed relative to itself."*** *(emphasis added). This was previously cited to applicant with respect to the 'mechanically free' feature.---"*

As noted above, however, this statement in Kormos is taken out of context and ignores the disclosure at Col. 3,ll 12-16:

> *"---The material (12, i. e., the 'reference mask' (or 'exoskeleton' as it is referred to by Kormos) is then stretched over and molded to the soft tissue region (of the patient) and affixed by clamps or other affixing means 14 to sides of the patient support--- " (emphasis added).*

Thus, the "locator" of Kormos is not "mechanically free" but rather is fixed to the patient support. It is difficult to imagine a clearer contraindication of the claimed invention than that of the very primary reference relied upon by the Examiner to reject the claims.

A legal conclusion of patent invalidity for obviousness must be supported by findings on the four factual inquiries set forth in Graham v. John Deere Co., [383 U.S. 1, 148 USPQ 459 (1966)]. Precedent clearly establishes that the fact-finder must make Graham findings before invalidating a patent for obviousness. See Jones v. Hardy, 727 F.2d 1524, 1529; 220 USPQ 1021,1025 (Fed. Cir. 1984)); Custom Accessories, Inc. v. Jefiftey-Allan Indus., Inc., 807 F.2d 955, 96 1, 1 USPQ2d 1196, 1200 (Fed. Cir. 1986); In Loctite Corp. v. Ultraseal Ltd., 781 F.2d. 861, 228 USPQ 90 (Fed. Cir. 1985), it was stated:

> *"---In patent cases, the need for express Graham findings takes on an especially significant role because of an occasional tendency --- to depart from the Graham test, and from the statutory standard of unobviousness that it helps determine, to the tempting but forbidden zone of hindsight. Thus, we must be convinced --- that--Graham (was actually applied)---"*

The necessity of Graham findings is especially important where the invention is less technologically complex, [In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999)]. In such a case, the danger increases that the very ease with which the invention can be understood may prompt one to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher. Thus, the legal conclusion of invalidity for obviousness depends on four factual inquiries identified by Graham v. John Deere Co. as concerning (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness. In the present case the Examiner has erred by failing to conduct a Graham analysis. Indeed the Examiner has failed to even mention Graham, much less analyze the disclosures of the prior art. In order to justify

a combination of references, it is necessary not only that it be physically possible to combine them, but also that the art should contain something to suggest the desirability of doing so. Ex parte Walker, 135 USPQ 195; Ex parte Fleischmann, 157 USPQ 155. The prior art cannot be combined as if appellant's invention was included therein as a part of the knowledge possessed by one of ordinary skill in the art. In combining references, the prior art references themselves must suggest their being combined so as to render the claimed invention obvious to one skilled in the art; and resort must not be had to applicant's own disclosure and the utilization of hindsight for the guiding hand that dictates the combination of references.

It is further well settled that the prior art itself must suggest the problem sought to be solved by the claimed invention before it can be said to suggest or disclose its solution. In re Shaffer, 108 USPQ 326; In re Authauser, 158 USPQ 351; US v. Adams 148 USPQ 479; In re Nomiya, 184 USPQ 607. Any analysis of obviousness must necessarily begin in the text of section 103, with the phrase "at the time the invention was made." For it is this phrase that guards against entry into the "tempting but forbidden zone of hindsight," [see Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861,873; 228 USPQ 90,98 (Fed. Cir. 1985), overruled on other grounds by Nobelpharma AB v. Implant Innovations, Inc., 141 F. 3dI 059, 46USPQ2d 1097 (Fed. Cir, 1998)], when analyzing the patentability of claims pursuant to that section.

Measuring a claimed invention against the standard established by section 103 requires the often difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. See, e.g., W.L. Gore & Assoc., Inc. v. Garlock, Inc., 721 F.2d 1540, 1553, 220 UPSQ 303, 313 (Fed. Cir 1983). Close adherence to this methodology is especially important in the case of less technologically complex inventions, where the very ease with which the invention can be understood may prompt one "to

fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher."

The present state of the patent law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc., 157 F. 3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998,) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding") In re Rouffet, 149 F.3d 1350, 1359; 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically --- the reasons one of ordinary skill in the art would have been 'motivated to select the references and combine them"); In re Fritch 972 F.2d 1260, 1265; 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the combination]"); In re Fine, 837 F.2d 1071, 1075; 5 USPQ2d 1596, 1600 (Fed Cir. 1988) (evidence of teaching or suggestion "essential" to avoid hindsight); Ashland Oil, Inc. v. Delta Resins, 776 F.2d 281, 297, 227 USPQ 657, 667 (Fed Cir. 1985) (district court's conclusion of obviousness was error when it did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). See also Graham 383 U.S. at 18, 148 USPQ at 467 ("strict observance" of factual predicates to obviousness conclusion required).

Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability-the essence of hindsight. See, e.g., Interconnect Planning Corp. v. Feil, 774 F.2d 1132 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case, the Board (Examiner) has obviously fallen into the hindsight trap.

Courts have noted that evidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved, see Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 1 F.3d 1568, 1573; 37 USPQ2d 1626, 1630 (Fed. Cir. 1996), Para-Ordinance Mfg. v. SGS Imports Intern., Inc., 73 F.3d 1085, 1088; 37 USPQ2d 1237, 1240 (Fed. Cir. 1995), although "the suggestion more often comes from the teachings of the pertinent references," Rouffet, 149 F.3d at 1355, 47 USPQ2d at 1456. The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be clear and particular. See, e.g., C R. Bard, 157 F.3d at 1352; 48 USPQ2d at 1232. Broad conclusory statements regarding the teachings of multiple references, standing alone, are not "evidence." Eg., McElmurry v. Arkansas Power &. Light Co., 995 F.2d 1576, 1578; 27 USPQ2d 1129, 1131 (Fed. Cir. 1993) ("Mere denials and conclusory statements, however, are not sufficient to establish a genuine issue of material fact."); In re Sichert, '566 F.2d 1154, 1164, 196 USPQ -209, 217 (CCPA 1977).

It is clear that the authorities are unanimous in holding that it is impermissible to use the claimed invention as an instruction manual or "template" to piece together isolated disclosures and teachings of the prior art so that the claimed invention may be rendered obvious. A rejection based on § 103 must rest on a factual basis, with the facts being interpreted without hindsight reconstruction of the invention from the prior art. In making this evaluation, the examiner has the initial duty of supplying the factual basis for the rejection he advances. He may not, because he doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis. See In re Warner, 379 F.2d 10 11, 10 17, 154 USPQ 173, 178 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968). Since there is no factual basis in the prior art relied on which supports the proposed combination thereof, and it is apparent that the examiner's

conclusion of obviousness is based on hindsight reconstruction of the claimed invention from isolated disparate teachings in prior art which is not concerned with the problem sought to be solved by the claimed invention, this ground of rejection is not sustainable.

It is clear that the Examiner, in making the analysis that led to the present ground of rejection, fell into the trap of hindsight reconstruction of the invention from the reference disclosures in light of applicant's specification.

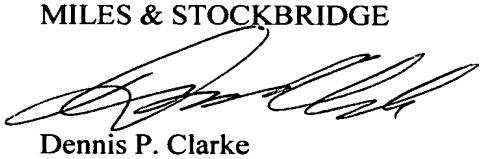
Accordingly, a reversal of this ground of rejection is respectfully requested.

CONCLUSION

It is respectfully requested that the final rejection of record be reversed and the application remanded to the Examiner for immediate allowance.

Respectfully submitted,

MILES & STOCKBRIDGE



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APPENDIX

CLAIMS ON APPEAL – SERIAL NO. 09/430,034

1. A medical method comprising the steps, not necessarily in order, of positioning a patient for a first medical procedure;

molding a locator to external features of a patient, the locator being placed in registry with a portion of the patient;

using at least 3 fiducial markers that are fixed relative to the locator a first time to get precise positioning information relative to at least part of the patient, the locator remaining mechanically free during this step;

performing a first medical procedure on the patient, the locator remaining mechanically free during this step;

after the first medical procedure, removing the locator from the patient;

at a later time after the removing of the locator, reattaching the locator to the patient, the locator again being in registry with the portion of the patient and having an identical relative to the portion of the patient as when the locator was previously attached;

after the re-attaching step, using the fiducial markers a second time to get precise positioning information relative to the at least part of the patient, the locator remaining mechanically free during this step; and

after the re-attaching step, performing a second medical procedure on the patient, the locator remaining mechanically free during this step.

2. The medical method of claim 1 wherein;

before performing the second medical procedure, the patient is positioned using a positioner independent of the locator to adjust and secure at least the portion of the patient in a desired position.

3. The medical method of claim 1 wherein the attaching and re-attaching of the locator is non-invasive.

4. The medical method of claim 3 wherein the locator is a face mask molded to fit in registry with the face of a specific patient.

5. The medical method of claim 4 wherein the face mask includes thermoplastic and the molding step includes the substeps of heating the thermoplastic and placing it on the face of a patient.

6. The medical method of claim5 further comprising the step of, after the molding step, attaching the at least 3 fiducial markers to the locator.

7. The medical method of claim 6 wherein the at least 3 fiducial markers are on a marker support and the attaching step includes fixing the marker support to the locator.

8. The medical method of claim1 wherein the locator is a face mask molded to fit in registry with the face of a specific patient, and further comprising the step of, after the molding step, attaching the at least 3 fiducial markers to the locator.

9. A method for performing a diagnostic imaging or a therapeutic medical procedure comprising the steps of, not necessarily in order:

putting a mechanically free locator on a patient, the locator including a face mask having at least 3 fiducial markers thereon;

placing the patient adjacent a medical device operable for performing the diagnostic imaging or therapeutic medical procedure on a patient, the locator remaining mechanically free during this step; and

sensing the positions of the fiducial markers when the patient is in a position for performing the diagnostic imaging or therapeutic medical procedure using the medical device, the locator remaining mechanically free during this step.

10. The method of claim 9 further comprising the step of molding the face mask to fit to the face of a specific patient.

11. The method of claim 10 wherein the molding step is performed by the placing of the face mask on the face of a specific patient.

12. The method of claim11 further comprising the step of, after the molding step, attaching the at least 3 fiducial markers to the locator.

13. The medical method of claim 12 wherein the at least 3 fiducial markers are on a marker support and the attaching step includes fixing the marker support to the locator.

14. A method of making a medical device that is a mechanically free locator comprising the steps of, not necessarily in order:

providing a locator having a face portion;

molding the face portion into a face mask corresponding to the face of a specific person and operable to register with the face of the specific person; and attaching at least 3 fiducial markers to the face mask, the fiducial markers operable to provide precise determination of the position of the patient.

15. A system for medical procedures, the system comprising:

a locator attachable to a patient, having at least 3 fiducial markers thereon, and having a registration portion for registration with a portion of a patient's body, the locator being mechanically free such that a patient is positionable without applying forces to the locator during patient positioning; and

wherein the locator is molded to fit external features of a specific patient.

16. The system of claim 15 further comprising a sensing subsystem for sensing the position of the at least 3 fiducial markers and an apparatus for applying therapeutic treatment to a patient; and wherein the sensing subsystem is operable to allow proper positioning of the patient in order to apply the therapeutic treatment to specific portions of the patient.

17. The system of claim 16 wherein the locator is a face mask molded to fit in registry with the face of a specific patient.

18. The system of claim 17 wherein the registration portion allows removal of the locator from the patient and re-attachment to the patient with an identical orientation relative to the portion of the patient as then the locator was previously attached.

19. A system for medical procedures, the system comprising:

a locator attachable to a patient, having at least 3 fiducial markers thereon;

a medical device for performing a diagnostic imaging or a therapeutic medical procedure on a patient; and

a sensing subsystem for sensing the positions of the fiducial markers when the patient is in a position for performing the medical procedure using the medical device; and

wherein the locator has a registration portion for registration with a portion of a patient's body, the locator being mechanically free such that a patient is positionable without applying forces to the locator during patient positioning; and wherein the locator is molded to fit external features of a specific patient.

20. The system of claim 19 wherein the locator is a face mask molded to fit in registry with the face of a specific patient.

21. The system of claim 20 wherein the registration portion allows removal of the locator from the patient and re-attachment to the patient with an identical orientation relative to the portion of the patient as when the locator was previously attached.

22. The system of claim 21 wherein the face mask includes thermoplastic molded to fit the face of a patient.

23. The system of claim 19 wherein the locator includes thermoplastic molded to fit a portion a portion of a patient.